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09/720,136	03/16/2001	Beverly B. Teter	UMARY3	7554

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EXAMINER	
OGUNBIYI, OLUWATOSIN A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/720,136	TETER, BEVERLY B.	
	Examiner	Art Unit	
	OLUWATOSIN OGUNBIYI	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,11,13-18,25,26,38,45 and 51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-11, 13-18, 25-26, 38, 45 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 9/2/08 has been entered into the record. Claims 1-9, 12, 19-24, 27-37, 39-44 and 46-50 have been cancelled. Claims 10-11, 13-18, 25-26, 38, 45 and 51 are pending and are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

New Rejections Based on Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1) Claims 10-11, 13-18, 25-26, 38, 45 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

Claim 10 is drawn to in an animal feed composition comprising crude protein and an antibiotic supplement, the improvement comprising replacing all or a portion of said antibiotic supplement with an anti-bacterial amount of an anti-microbial fatty acid component, comprising an amount of lauric acid effective to provide said feed composition with a lauric acid concentration between 0.5 and 10%.

Applicants point to page 4 lines 25-28 for support for the amendment to claim 10 which is underlined. This portion of the specification reads:

According to the invention, sufficient high lauric acid oil will be included in the diet of the chickens such that lauric acid will preferably comprise about 0.5 % to about 10 % of the diet, more preferably about 2 % to about 7%, and most preferably about 3 % to about 5 %.

The amendment to the claim "provides said feed composition with a lauric acid concentration between 0.5 and 10%" does not find support in this portion of the specification because the portion of the specification cited teaches that the amount of lauric acid is *a percentage of the diet or feed* and but the amendment implies that that the lauric acid concentration applied or provided (via anti-microbial fatty acid component) in the feed is at a concentration of between 0.5 to 10%. The lauric acid amount *being a percentage of the feed* is different from *providing the feed with 0.5% to 10% concentration of lauric acid.*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2) Claims 10-11, 13-18, 25-26, 38, 45 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 as amended is now drawn to in an animal feed composition comprising crude protein and an antibiotic supplement, the improvement comprising replacing all or a

portion of said antibiotic supplement with an anti-bacterial amount of an anti-microbial fatty acid component, comprising an amount of lauric acid effective to provide said fee a lauric acid concentration between 0.5 and 10%.

The metes and bounds of *providing said feed composition with lauric acid concentration between 0.5 and 10%* is vague and indefinite. This can be interpreted two ways in the claim: Is the lauric acid 0.5 to 10% of the feed composition (see specification p. 4 lines 25-28) or is the feed composition provided with a composition (antimicrobial fatty acid component) comprising a lauric acid concentration of 0.5 to 10%? If the latter case is the case, if the feed composition is provided with a lauric acid concentration between 0.5 to 10%, what is the final concentration of lauric acid in the animal feed?

Rejections Withdrawn

3) The rejection of claim 13 under 35 U.S.C. 112, second paragraph is withdrawn in view of the amendment to the claim.

4) The rejection of claim 11 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the amendment to the claims.

5) The rejection of claim 12 under 35 U.S.C. 102(b) as being anticipated by Schroeder et al. US 4,169,041, July 3, 1979 is withdrawn in view of the cancellation of the claim.

6) The rejection of claim 12 under 35 U.S.C. 103(a) as being unpatentable over Schroeder et al. US 4,169,041, July 3, 1979 in view of 21 CFR section 558.15 1997 (New animal drugs for use in animal feeds – antibiotic, nitroduran and sulfonamide drugs in the feed of animals) and J. Raloff, July 1998, Science News vol. 154 p. 39) is withdrawn in view of the cancellation of the claim.

Rejections Maintained

7) The rejection of claims 10-13, 18, 38 and 45 under 35 U.S.C. 102(b) as being anticipated by Schroeder et al. US 4,169,041, July 3, 1979 is maintained for reasons made of record in the last office actions filed 7/2/07 and 3/31/08.

Applicant's arguments

Applicant argues the MPEP states that when a compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various items from a list of alternatives given, anticipation can only be found if the classes of items are sufficiently limited or well delineated. (MPEP §2131.02). In Petering, the prior art disclosed a generic chemical formula "wherein X, Y, Z, P, and R' represent either hydrogen or alkyl radicals, or a side chain containing an OH group." (*In re Petering* 301 F.2d 676). The court held that this formula, without more, could not anticipate a claim to a specific compound because the generic formula encompassed a vast number of possible compounds.

Applicant argues that in this case, Schroeder et al. discloses a number of possible ingredients for inclusion in an animal feed supplement, yet does not literally identify what is claimed in the instant application. In Schroeder et al., possible ingredients for its disclosed animal feed include a sugar source, a phosphate source, a metal oxide, an emulsifier, preservatives, a fat source, and an antibiotic supplement. Schroeder et al. then continues to list potential specific items for each possible generic ingredient, i.e., possible fat sources include yellow grease, palm oil, and/or mixed vegetable oils. By listing a number of potential specific items for each generic ingredient, Schroeder et al. provides a vast number of specific animal feed compositions that could be created from its generic list of ingredients. Although Schroeder discloses a few specific animal feed composition, it fails to specifically disclose the animal feed composition of the instant claims.

The response:

Applicant's arguments have been carefully considered but are not persuasive. Applicants attention is drawn to the same section of the MPEP (MPEP §2131.02) cited which states that "when a compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them… anticipation can only be found if classes of items are sufficiently limited *or* well delineated. Schroeder et al clearly delineates all the necessary components of the animal feed composition including the fat source. Schroeder et al clearly delineates possible fat sources in the animal feed composition as set forth below:

The Fat Ingredient

The fats and oils that can be employed in the invention as a source of animal edible fat are the edible, water insoluble fats and oils from animal and vegetable sources which can be liquids or solids at room temperature. The compositions can contain from 2 to about 30, preferably from 5 to about 20 weight percent edible fat. These fats are various fatty acids such as stearic, palmitic, oleic, linoleic, lauric, etc., and the mono-, di- or tri- glycerides of these fatty acids…**The fats are commonly identified by source and suitable fats which can be employed include the oils, tailings or residues of the following: soybean oil, cottonseed oil, sesame oil, olive oil, corn oil, tallow, fish oil, coconut oil, palm oil, etc. Preferably, relatively inexpensive sources of fats are employed such as the yellow grease compositions** which are reclaimed restaurant fats and greases, acidulated soap stocks or acidulated fats and oils. See column 5 lines 45 to 68.

Schroeder clearly delineates a fat source i.e. high in lauric acid i.e. coconut oil. Furthermore, Schroeder et al lists only a limited number of fat sources i.e. 10 fat sources and one of skill in the art can clearly envisage coconut oil in the 10 fat sources listed. **Same portion of MPEP 2131.02 cited by Applicant states : A generic chemical formula will anticipate a claimed species covered by the formula when the specie can be "at once envisaged" from the formula"... If one of ordinary skill in the art is able to "at once envisage " the specific**

compound within the generic formula the compound is anticipated. One of ordinary skill in the art must be able to drawn the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be at once envisaged. In the instant case, Schroeder clearly delineates the composition of the animal feed composition as follows in table 1 of column 2 lines 55 to 65:

ingredients in the composition of the invention:

TABLE 1

COMPONENT	BROAD			PREFERRED		
1. Sugar source	15	-	93%	25	-	80%
2. Phosphate source (as P_2O_5)	0.1	-	30%	5	-	20%
3. Metal Oxide	0.5	-	5%	0.8	-	3%
4. Fat source	0.0	-	30%	5	-	20%
5. Emulsifier	0.05	-	1.0%			
6. Starch	0.0	-	0.0	0.0	-	1.0%
7. Protein or Equivalent Protein	0.0	-	40.0%	5.0	-	40%
8. Minerals, vitamins	0.0	-	1.0%	0.1	-	0.5%
9. Preservatives	0.05	-	8.0%	0.1	-	5.0%

Schroeder et al also teaches the type of fat source including coconut oil as set forth above and teaches in the table above that the fat source is 0% to 30% of the feed composition or preferred amount is 5 to 20 % of the feed composition. The instant specification teaches that coconut oil contains 50 % lauric acid (specification p. 4 lines 4-6), thus the composition of Schroeder et al comprises lauric acid in the amount of 2.5% to 10% of the feed composition. Thus, one of ordinary skill in the art is able to write the name of each of the compounds and the amounts included in the generic formula of Schroeder et al including the fat source i.e. coconut oil. Thus, Schroeder still anticipates the instant claims.

8) The rejection of claims 10-14, 15-18, 25, 26,38,45 and 51 under 35 U.S.C. 103(a) as being unpatentable over Schroeder et al. US 4,169,041, July 3, 1979 in view of 21 CFR section 558.15 1997 (New animal drugs for use in animal feeds – antibiotic, nitroduran and sulfonamide drugs in the feed of animals) and J. Raloff, July 1998, Science News vol. 154 p. 39) is maintained for reasons made of record in the previous office action filed 7/2/07 and 3/31/08.

Applicants urge that Raloff is not prior art against the present application because the present application claims priority to US provisional 60/090,303 filed June 23 1998 and Raloff is dated July 18, 1998. Applicants argue that the instantly claimed animal feed composition as claimed in claims 10-18, 25, 26, 38, 45 and 51 is disclosed in the '303 priority application on pages 3, lines 1-4 and page 8, lines 1-19.

The pages of the priority application cited have been carefully examined as is the rest of the priority application but no support is found for the invention as claimed in claims 10-18, 25, 26, 38, 45 and 51.

Page 3 lines 1-4 of the '303 priority application is as follows:

This invention proposes using coconut and other natural sources of lauric acid and its derivatives as a food supplement for production animals to lower, or eliminate, the need for anti-biotic use. Furthermore the short chain fatty acids are used by

Independent claim 10 recites: In an animal feed composition comprising crude protein and an antibiotic supplement, the improvement comprising replacing all or a portion of said antibiotic supplement with an anti-bacterial amount of an anti-microbial fatty acid component, comprising an amount of lauric acid effective to provide said feed a lauric acid concentration between 0.5 and 10%.

The portion of priority application cited above does not provide support for the animal feed composition of claim 10, comprising an amount of lauric acid effective to provide said feed a lauric acid concentration between 0.5 and 10%.

Page 8 lines 1-19 of the '303 priority application is as follows:

APPLICATIONS OF THE TECHNOLOGY

List all products you envision resulting from this invention and whether these products can be developed in the near term (less than two years) or long term.

Near term products would include animal feeds. Most feeds have oil added in some form - often "street grease" from the restaurant trade. With the advent of synthetic fats, such as o1estra, this source could be compromised for animal feeds. Coconut oil or by products which also could contain some protein could be formulated into the animal feed. Appropriate ingestion levels would need to be determined for different species at the farm level. These fatty acids could also be fed as a calcium/magnesium salt to provide mineral supplement without being greasy. Pet foods - dog, cat, bird, fish, reptile etc could be developed. The triglyceride fat, monoglyceride - monolauren, or byproducts containing plant materials rich in CI0,12,14, or 16:1 and C18:1 and polyunsaturated fatty acids could be used alone or mixed.

Independent claim 10 recites: In an animal feed composition comprising crude protein and an antibiotic supplement, the improvement comprising replacing all or a portion of said antibiotic supplement with an anti-bacterial amount of an anti-microbial fatty acid component, comprising an amount of lauric acid effective to provide said feed a lauric acid concentration between 0.5 and 10%.

The portion of priority application cited above does not provide support for the animal feed composition of claim 10, comprising an amount of lauric acid effective to provide said feed a lauric acid concentration between 0.5 and 10%.

While, the priority application discloses the use of lauric acid containing oils in animal feed to replace *to lower, or eliminate, the need for anti-biotic use*, the priority application does not disclose the lauric acid concentration between 0.5 and 10% or that the lauric acid in the fatty acid component comprises 2% to 10% of the animal feed. Thus, Raloff is deemed prior art and the instant claims are obvious over the combination of Schroeder et al and 21 CFR section 558.15, 1997 and J. Raloff, July 1998, Science News vol. 154 p. 39).

9) The rejection of claims 10 and 11 under 35 U.S.C. 103(a) as being unpatentable over Schroeder et al. US 4,169,041, July 3, 1979 in view of Williams et al. US 5,378,477, Jan. 3, 1995 is maintained for reasons made in the office action mailed 3/31/08.

Applicants arguments are essentially for the same reasons set forth above for Schroeder et al. Applicants arguments for Schroeder et al have been addressed above and were not persuasive, thus this instant rejection is still maintained.

10) The rejection of claim 11 under 35 U.S.C. 103(a) as being unpatentable over Schroeder et al. US 4,169,041, July 3, 1979 and Williams et al. US 5,378,477, Jan. 3, 1995 as applied to claims 10 and 11 above further in view of the publication: Biotechnology Consultation Memorandum of Video-Conference BNF NO. 000025, April 4, 1995 (http://www.cfscan.fda.gov/~rdb/bnfm025.html is maintained for reasons made in the office action mailed 3/31/08.

Applicants arguments are essentially for the same reasons set forth above for Schroeder et al. Applicants arguments for Schroeder et al have been addressed above and were not persuasive, thus this instant rejection is still maintained.

Status of Claims

Claims 10-11, 13-18, 25-26, 38, 45 and 51 are rejected. No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUWATOSIN OGUNBIYI whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am- 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Oluwatosin Ogunbiyi/
Examiner, Art Unit 1645

/Robert B Mondesi/
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